TDMS No. 99023 - 03 Test Type: CHRONIC Route: GAVAGE P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

beta-Myrcene

**CAS Number:** 123-35-3

**Date Report Requested:** 08/15/2008 **Time Report Requested:** 14:01:25 **First Dose M/F:** 03/25/02 / 03/26/02

Lab: BAT

Species/Strain: RATS/F 344

F1\_Rev.2\_R2

**C Number:** C99023

**Lock Date:** 12/22/2004

Cage Range: ALL

Date Range: ALL

**Reasons For Removal:** ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

**TDMSE Version:** 2.0.0

beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Disposition Summary				
Animals Initially in Study Early Deaths	50	50	50	50
Dosing Accident	40	1	40	1
Moribund Sacrifice Natural Death	18 3	8 5	13 9	24 25
Survivors	3	3	9	25
Terminal Sacrifice	29	36	28	
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Inflammation, Chronic		4 (00()	1 (2%)	4 (00()
Perforation Muscularis, Periesophageal Tissue,		1 (2%)		1 (2%) 1 (2%)
Hemorrhage				I (∠70)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Inflammation, Chronic	(00)	(00)	1 (2%)	(88)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation, Chronic	. ,	` ,	1 (2%)	` ,
Parasite Metazoan	1 (2%)	1 (2%)	2 (4%)	
Intestine Large, Rectum	(50)	(50)	(50)	(48)
Inflammation, Chronic			1 (2%)	
Parasite Metazoan	6 (12%)	4 (8%)	3 (6%)	4 (00/)
Ulcer	(40)	(50)	(FO)	1 (2%)
Intestine Small, Duodenum Intestine Small, Ileum	(49) (50)	(50) (50)	(50) (50)	(50) (50)
Parasite Metazoan	(50) 1 (2%)	(30)	(50)	(30)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Angiectasis	2 (4%)	4 (8%)	3 (6%)	(50)
Basophilic Focus	23 (46%)	12 (24%)	5 (10%)	2 (4%)
Clear Cell Focus	14 (28%)	19 (38%)	9 (18%)	2 (470)
Degeneration, Cystic	1 (2%)	1 (2%)	3 (1070)	
Eosinophilic Focus	6 (12%)	5 (10%)	3 (6%)	
Fatty Change	4 (8%)	4 (8%)	2 (4%)	
Hemorrhage	. (3,3)	. (3,3)	= ( . / • /	1 (2%)
Hepatodiaphragmatic Nodule	3 (6%)	3 (6%)	2 (4%)	3 (6%)
Inflammation, Chronic	34 (68%)	36 (72%)	19 (38%)	1 (2%)
Mixed Cell Focus	6 (12%)	1 (2%)	` ,	,
Necrosis	` '	4 (8%)	4 (8%)	4 (8%)

TDMS No. 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

a - Number of animals examined microscopically at site and number of animals with lesion

Route: GAVAGE **CAS Number:** 123-35-3 Species/Strain: RATS/F 344

**TDMS No.** 99023 - 03 Test Type: CHRONIC Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Regeneration		1 (2%)			
Bile Duct, Hyperplasia	39 (78%)	42 (84%)	39 (78%)	6 (12%)	
Centrilobular, Degeneration	3 (6%)	1 (2%)	1 (2%)		
Hepatocyte, Hypertrophy	1 (2%)			30 (60%)	
Serosa, Hyperplasia		1 (2%)			
Serosa, Inflammation, Suppurative			1 (2%)		
Mesentery	(13)	(8)	(5)	(3)	
Fat, Necrosis	12 (92%)	7 (88%)	4 (80%)	3 (100%)	
Oral Mucosa	(2)	(0)	(0)	(0)	
Inflammation, Chronic	1 (50%)				
Pancreas	(50)	(50)	(50)	(50)	
Inflammation, Granulomatous	1 (2%)				
Necrosis	1 (2%)				
Acinus, Atrophy	9 (18%)	14 (28%)	11 (22%)	5 (10%)	
Acinus, Hyperplasia	8 (16%)	7 (14%)	2 (4%)		
Artery, Inflammation, Chronic			1 (2%)		
Artery, Thrombosis				1 (2%)	
Duct, Cyst	2 (4%)	3 (6%)	5 (10%)	, ,	
Salivary Glands	(50)	(50)	(50)	(48)	
Atrophy				1 (2%)	
Cyst		1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Erosion	1 (2%)			3 (6%)	
Fibrosis			1 (2%)		
Inflammation, Chronic Active	5 (10%)	3 (6%)	12 (24%)	27 (54%)	
Ulcer	2 (4%)	2 (4%)	5 (10%)	18 (36%)	
Serosa, Hyperplasia				1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Inflammation, Chronic	3 (6%)	7 (14%)	2 (4%)		
Mineralization	1 (2%)		1 (2%)		
Ulcer	1 (2%)	2 (4%)	1 (2%)	1 (2%)	
Epithelium, Ectasia	14 (28%)	27 (54%)	33 (66%)	14 (28%)	
Epithelium, Hyperplasia	1 (2%)	2 (4%)	1 (2%)		
RDIOVASCULAR SYSTEM					
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	39 (78%)	43 (86%)	42 (84%)	38 (76%)	
Atrium, Thrombosis	2 (4%)		2 (4%)		
Endocardium, Hyperplasia				1 (2%)	
Epicardium, Hyperplasia				1 (2%)	
Myocardium, Mineralization			1 (2%)	1 (2%)	
Valve, Thrombosis			2 (4%)	• '	

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99023 - 03 Test Type: CHRONIC

Route: GAVAGE Species/Strain: RATS/F 344

Inflammation, Chronic

Inflammation, Chronic Active

beta-Myrcene
CAS Number: 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
(50)	(50)	(50)	(50)	
3 (6%)		9 (18%)	1 (2%)	
	2 (4%)		1 (2%)	
13 (26%)	16 (32%)	15 (30%)	7 (14%)	
	1 (2%)			
(50)	(50)	(50)	(50)	
9 (18%)	9 (18%)	13 (26%)		
(50)	(50)	(50)	(50)	
1 (2%)				
(45)	(47)	(48)	(45)	
		1 (2%)	2 (4%)	
(50)	(49)	(50)		
8 (16%)	8 (16%)	9 (18%)	1 (2%)	
6 (12%)	9 (18%)	5 (10%)	2 (4%)	
15 (30%)				
(50)		(50)		
1 (2%)	,	1 (2%)	,	
,		, ,	1 (2%)	
20 (40%)	18 (36%)	15 (30%)	1 (2%)	
	2 (4%)	3 (6%)	` ,	
•	(50) 3 (6%) 13 (26%) (50) 9 (18%) (50) 1 (2%) (45) (50) 8 (16%) 6 (12%) 15 (30%) (50) 1 (2%)	(50) (50) (50) (3 (6%) 5 (10%) 2 (4%) 13 (26%) 16 (32%) 1 (2%) (50) (50) 9 (18%) (50) (50) 1 (2%) (45) (47) (50) (49) 8 (16%) 6 (12%) 9 (18%) 15 (30%) (11 (22%) (50) 1 (2%)	(50) (50) (50) (50) 3 (6%) 5 (10%) 9 (18%) 2 (4%)  13 (26%) 16 (32%) 15 (30%) 1 (2%) (50) (50) (50) 9 (18%) 9 (18%) 13 (26%) (50) 1 (2%) (45) (47) (48)  (50) (49) (50) 8 (16%) 8 (16%) 9 (18%) 6 (12%) 9 (18%) 5 (10%) 15 (30%) 11 (22%) 10 (20%) (50) 1 (2%) (50) (50) (50)	(50) (50) (50) (50) (50) (50) (50) (50)

GENITAL SYSTEM				
Epididymis Granuloma Sperm	(50)	(50)	(50) 1 (2%)	(48)
Inflammation, Chronic			1 (2%)	
Vacuolization Cytoplasmic, Focal	1 (2%)		, ,	
Preputial Gland	(50)	(50)	(50)	(47)
Atrophy	1 (2%)			
Cyst	1 (2%)			
Hyperplasia	1 (2%)	2 (4%)		
Inflammation, Chronic	42 (84%)	44 (88%)	43 (86%)	36 (77%)
Prostate	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Hyperplasia	7 (14%)	3 (6%)	6 (12%)	1 (2%)

4 (8%)

1 (2%)

8 (16%)

6 (12%)

6 (12%)

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99023 - 03 Test Type: CHRONIC Route: GAVAGE

Species/Strain: RATS/F 344

beta-Myrcene
CAS Number: 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Necrosis				1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)	
Atrophy	(50)	(50)	(50)	1 (2%)	
Testes Interstitial Cell, Hyperplasia	(50) 6 (12%)	(50) 2 (4%)	(50) 2 (4%)	9 (19%)	
EMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hyperplasia Lymph Node	8 (16%) (3)	5 (10%)	7 (14%)	1 (2%)	
Mediastinal, Ectasia	(3) 1 (33%)	(5)	(6)	(0)	
Mediastinal, Hemorrhage	. (3070)	1 (20%)	1 (17%)		
Mediastinal, Hyperplasia, Lymphoid		2 (40%)	, ,		
Mediastinal, Pigmentation, Hemosiderin	(0)	1 (20%)	1 (17%)	(0)	
Lymph Node, Mandibular Lymph Node, Mesenteric	(0) (50)	(0) (50)	(1) (50)	(0) (50)	
Pigmentation, Hemosiderin	(50)	(30)	(30)	1 (2%)	
Spleen	(50)	(50)	(50)	(50)	
Atrophy	1 (2%)	2 (4%)	6 (12%)	46 (92%)	
Congestion	2 (00/)		2 (4%)		
Fibrosis Hematopoietic Cell Proliferation	3 (6%) 8 (16%)	6 (12%)	4 (8%)		
Infarct	0 (1070)	0 (1270)	1 (2%)		
Necrosis, Focal		1 (2%)	1 (2%)		
Thymus	(47)	(50)	(48)	(47)	
Atrophy	40 (85%)	42 (84%)	43 (90%)	44 (94%)	
Inflammation, Suppurative Epithelial Cell, Hyperplasia		1 (2%)	1 (2%)		
			1 (270)		
NTEGUMENTARY SYSTEM		4-0	(12)	(7.1)	
Mammary Gland	(50)	(50)	(49)	(50)	
Cyst Inflammation, Chronic			1 (2%) 1 (2%)		
Skin	(50)	(50)	(50)	(50)	
Hyperkeratosis	(/	1 (2%)	1 (2%)	ζ/	
Inflammation, Chronic			1 (2%)		
Ulcer		4 (00/)	1 (2%)		
Subcutaneous Tissue, Inflammation, Granulomatous		1 (2%)			
Ciandiomatous					

# MUSCULOSKELETAL SYSTEM

beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Bone	(50)	(50)	(50)	(50)	
Skeletal Muscle	(1)	(1)	(1)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hydrocephalus Cerebrum, Compression	3 (6%)	1 (2%)			
Hypothalamus, Compression Neuron, Necrosis, Focal	1 (2%)		1 (2%)		
Peripheral Nerve	(2)	(0)	(0)	(0)	
Axon, Degeneration	1 (50%)				
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Inflammation Inflammation, Chronic	32 (64%) 1 (2%)	33 (66%)	18 (36%)	14 (28%)	
Metaplasia, Osseous Alveolar Epithelium, Hyperplasia	5 (10%) 9 (18%)	9 (18%)	1 (2%) 2 (4%)	2 (4%) 4 (8%)	
Alveolus, Emphysema	1 (2%)			. ,	
Nose Dysplasia	(50)	(50)	(50) 1 (2%)	(50)	
Inflammation, Chronic Active	14 (28%)	19 (38%)	27 (54%)	35 (70%)	
Ulcer Olfactory Epithelium, Degeneration	45 (90%)	49 (98%)	1 (2%) 47 (94%)	49 (98%)	
Trachea Peritracheal Tissue, Inflammation, Chronic	(50)	(50) 1 (2%)	(50)	(50)	
· · · · · · · · · · · · · · · · · · ·		(270)			
SPECIAL SENSES SYSTEM					
Eye Cataract	(50) 1 (2%)	(50)	(50)	(50)	
Anterior Chamber, Inflammation, Suppurative	. (=/3)	1 (2%)			
Cornea, Inflammation, Suppurative Retina, Degeneration		1 (2%) 1 (2%)			
Sclera, Metaplasia, Osseous Harderian Gland	23 (46%) (50)	25 (50%) (50)	30 (60%) (50)	6 (12%) (49)	
Atrophy		1 (2%)	(30)	1 (2%)	
Cyst Hyperplasia	1 (2%) 1 (2%)	2 (4%)		1 (2%)	
Inflammation, Chronic	2 (4%)	1 (2%)	50 (4000()	2 (4%)	
Pigmentation, Porphyrin	50 (100%)	50 (100%)	50 (100%)	49 (100%)	

TDMS No. 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

a - Number of animals examined microscopically at site and number of animals with lesion

beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Zymbal's Gland	(0)	(1)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hydronephrosis Inflammation, Suppurative, Focal Inflammation, Chronic	1 (2%) 1 (2%) 1 (2%)	22 (44%)	22 (44%)	
Metaplasia, Osseous	(=10)	4 (00()	1 (2%)	
Mineralization Necrosis	1 (2%)	1 (2%) 2 (4%)	2 (4%)	
Nephropathy Pigmentation	45 (90%) 1 (2%)	48 (96%)	48 (96%)	49 (98%)
Papilla, Mineralization	1 (2%)	48 (96%)	40 (80%) 2 (4%)	4 (8%)
Renal Tubule, Cyst Renal Tubule, Hyperplasia	1 (2%)	3 (6%)	2 (4%)	
Renal Tubule, Hyperplasia, Oncocytic		3 (6%)		
Renal Tubule, Nephrosis		42 (84%)	46 (92%)	48 (96%)
Transitional Epithelium, Hyperplasia		21 (42%)	19 (38%)	18 (36%)
Vein, Thrombosis Urinary Bladder	(50)	(50)	3 (6%) (50)	3 (6%) (49)
Inflammation	(30)	(30)	(30)	1 (2%)

\*\*\* END OF MALE \*\*\*

TDMS No. 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99023 - 03 Test Type: CHRONIC

Route: GAVAGE Species/Strain: RATS/F 344 beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Disposition Summary
Animals Initially in Study 50 50 50 50 Early Deaths
Accidently Killed 1
Dosing Accident 1 1
Moribund Sacrifice         11         9         12         7           Natural Death         8         6         10         9
Survivors
Terminal Sacrifice 31 33 28 33
Animals Examined Microscopically 50 50 50 50
ALIMENTARY SYSTEM
Esophagus (50) (50) (49) (50)
Perforation 1 (2%)
Muscularis, Inflammation, Chronic  1 (2%)
Intestine Large, Colon (50) (50) (50) (50) (50)  Parasite Metazoan 1 (2%) 1 (2%)
Parasite Metazoan 1 (2%) 1 (2%) Ulcer 1 (2%)
Intestine Large, Rectum (50) (50) (50) (50)
Parasite Metazoan 1 (2%) 5 (10%) 5 (10%) 2 (4%)
Ulcer 1 (2%)
Intestine Small, Duodenum (50) (50) (49) (50)
Intestine Small, Ileum (50) (50) (49) (50)
Epithelium, Hyperplasia, Focal 1 (2%) Liver (50) (50) (49) (50)
Angiectasis 1 (2%) (30) (45) (30)
Basophilic Focus 44 (88%) 43 (86%) 42 (86%) 31 (62%)
Clear Cell Focus 4 (8%) 6 (12%) 6 (12%) 8 (16%)
Eosinophilic Focus 6 (12%) 10 (20%) 15 (31%) 24 (48%)
Fatty Change 3 (6%) 3 (6%) 4 (8%) 1 (2%)
Fibrosis 2 (4%)
Hemorrhage       1 (2%)         Hepatodiaphragmatic Nodule       6 (12%)       5 (10%)       6 (12%)       8 (16%)
Inflammation, Chronic 41 (82%) 41 (82%) 41 (84%) 33 (66%)
Mineralization 41 (02/8) 41 (02/8) 41 (02/8) 41 (02/8) 41 (02/8)
Mixed Cell Focus 6 (12%) 5 (10%) 3 (6%) 6 (12%)
Necrosis 2 (4%) 1 (2%) 1 (2%) 1 (2%)
Regeneration 1 (2%)
Bile Duct, Cyst 1 (2%)
Bile Duct, Hyperplasia 8 (16%) 11 (22%) 12 (24%) 11 (22%) 12 (24%) 13 (22%) 14 (29%) 14 (29%) 15 (24%) 15 (24%) 15 (24%) 16 (24%) 16 (24%) 16 (24%) 17 (24%) 17 (24%) 17 (24%) 18 (24%)
Centrilobular, Degeneration 1 (2%) 2 (4%) 1 (2%)

a - Number of animals examined microscopically at site and number of animals with lesion

**TDMS No.** 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Centrilobular, Necrosis   1 (2%)	SCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Sinusoid, Congestion   1 (2%)	Centrilobular, Necrosis			2 (4%)		
Mesentery   (7)		1 (2%)		,		
Fat, Necrosis 6 (86%) 13 (100%) 7 (100%) 9 (100%) Oral Mucosa (1) (0) (0) (0) Pancreas (50) (50) (49) (50) Acinus, Atrophy 9 (18%) 9 (18%) 10 (20%) 3 (6%) Acinus, Hyperplasia 1 (2%) Duct, Cyst 3 (6%) 2 (4%) 1(2%) Duct, Cyst 3 (6%) 2 (4%) (50) Asinusy Glands (50) (49) (49) (50) Hyperplasia (50) (50) (49) (49) (50) Hyperplasia (50) (50) (49) (50) Inflammation, Chronic Active (50) (50) (50) (49) (50) Ulcer (50) (50) (49) (50) Inflammation, Chronic Active (50) (50) (48) (50) Inflammation, Chronic (50) (50) (48) (50) Inflammation, Chronic (50) (50) (48) (50) Inflammation, Chronic (50) (50) (49) (50) Inflammation, Chronic (50) (50) (49) (50) Inflammation, Chronic (50) (50) (50) (50) (50) (50) (50) (50) Inflammation, Chronic (50) (50) (50) (50) (50) (50) (50) (50)	Sinusoid, Infiltration Cellular, Histiocyte	1 (2%)				
Oral Mucosa (1) (0) (0) (55) Pancresa (50) (50) (50) (49) (55) Acinus, Atrophy 9 (18%) 9 (18%) 10 (20%) 3 (6%) Acinus, Atrophy 10 (2%) 3 (6%) Acinus, Atrophy 11 (2%) Duct, Cyst 3 (6%) 2 (4%) 3 (6%) 4 (8%) Salivary Glands (50) (49) (50) Hyperplasia 1 (2%) 1 (2%) 1 (2%) (50) Hyperplasia 1 (2%) 1 (2%) 2 (4%) 3 (6%) Hyperplasia 1 (2%) 1 (2%) 2 (4%) 3 (6%) Hyperplasia 1 (2%) 1 (2%) 1 (2%) 1 (2%) Inflammation, Chronic Active 1 (2%) 1 (2%) 1 (2%) 1 (2%) 1 (2%) Inflammation, Chronic Active 1 (2%) 4 (8%) 1 (2%) 1 (2%) Hingard, Glandular (50) (50) (49) (50) Hingard, Glandular (50) (50) (49) (50) Hingard, Glandular (50) (50) (49) (50) Epithelium, Ectasia 38 (76%) 39 (78%) 36 (73%) 38 (76%) Epithelium, Hyperplasia 1 (2%) Tongue (1) (0) (1) (0) (1) (0)  CARDIOVASCULAR SYSTEM  Heat (50) (50) (49) (50) Cardiomyopathy 43 (66%) 31 (62%) 30 (61%) 34 (68%) Fibrosis 1 (2%) Altium, Thrombosis Myocardium, Inflammation, Chronic 1 (2%) Valve, Inflammation, Chronic 1 (2%)  ENDOCRINE SYSTEM  Adrenal Cortex (50) (50) (50) (50) (50) Adrenal Cortex (50) (50) (50) (50) (50) Adrenal Cortex (50) (50) (50) (50) (50) Adrenal Medulla (50) (50) (50) (50) (50) Adrenal Medulla (50) (50) (50) (50) (50) Hyperplasia (50) (60) (40) (40) Hyperplasia (50) (47) (48) (47) (45)			(13)	(7)	(9)	
Pancreas (50) (50) (49) (50) Acinus, Atrophy 9 (18%) 9 (18%) 10 (20%) 3 (6%) Acinus, Hyperplasia 1 (2%) 1 (2%) Duct, Cyst 3 (6%) 2 (4%) 3 (6%) 4 (8%) Salivary Glands (50) (49) (49) (50) Hyperplasia (12%) Stomach, Forestomach (50) (50) (49) (50) Inflammation, Chronic Active (12%) 1 (2%) 3 (6%) Ulcer (50) (50) (49) (50) Stomach, Glandular (50) (50) (49) (50) Mineralization 1 (2%) 4 (8%) 1 (2%) (50) Mineralization 1 (2%) 4 (8%) 1 (2%) (50) Mineralization 1 (2%) 4 (8%) 1 (2%) Epithelium, Hyperplasia 38 (76%) 39 (78%) 36 (73%) 38 (76%) Epithelium, Hyperplasia (10) (0) (1) (0)  **ARDIOVASCULAR SYSTEM**  Heart (50) (50) (49) (50) Cardiomyopathy 43 (86%) 31 (62%) 30 (61%) 34 (68%) Fibrosis 1 (2%) Myocardium, Inflammation, Chronic 1 (2%) Wivecardium, Inflammation, Chronic 1 (2%)  **NDOCRINE SYSTEM**  Addreal Cortex (50) (50) (50) (50) (50) Nyocardium, Inflammation, Chronic 1 (2%)  **NDOCRINE SYSTEM**  Addreal Cortex (50) (50) (50) (50) (50) Necrosis 1 (2%) Nacrosis 1 (2%) 1 (2%) 1 (2%) 1 (2%) 1 (2%) Nacrosis 1 (2%) 1 (						
Acinus, Atrophy			(0)	(0)	(0)	
Acinus, Hyperplasia 1 (2%) 1 (2%) 1 (2%) 3 (6%) 4 (8%) 5 (50) 4 (49) (49) (50) 4 (89) (50) (50) (50) (50) (50) (50) (50) (50						
Duct, Cyst 3 (6%) 2 (4%) 3 (6%) 4 (8%) Salivary Glands (50) (49) (49) (50) Hyperplasia (50) (50) (50) (49) (50) Inflammation, Chronic Active (50) (50) (49) (50) Inflammation, Chronic Active (50) (50) (49) (50) Inflammation, Chronic (50) (50) (10) (10) (10)  CARDIOVASCULAR SYSTEM  Heart (50) (50) (50) (49) (50) Cardiomyopathy (43 (86%) 31 (62%) 30 (61%) 34 (68%) Fibrosis (50) (50) (50) (50) (50) Inflammation, Chronic (50) (50) (50) (50) (50) Inflammation, Chronic (50) (50) (50) (50) (50) (50) Inflammation, Chronic (50) (50) (50) (50) (	Acinus, Atrophy		9 (18%)		3 (6%)	
Salivary Glands (50) (49) (59) (50) (50) (49) (50) (50) (50) (50) (50) (50) (50) (50	Acinus, Hyperplasia	1 (2%)	0 (40()	1 (2%)	4 (00()	
Hyperplasia   1 (2%)   1 (2%	Juct, Cyst			3 (6%)	4 (8%)	
Stomach, Forestomach   (50)   (50)   (49)   (50)   (50)   (10)	Ilivary Giands	(50)	(49)	(49)		
Inflammation, Chronic Active 1 (2%) 1 (2%) 2 (4%) 3 (6%) Ulcer 1 (2%) 1	amach Forostomach	(50)	(50)	(40)	(50)	
Ulcer						
Stomach, Glandular   (50)		1 (270)	1 (278)			
Mineralization		(50)	(50)			
Epithelium, Ectasia 38 (76%) 39 (78%) 36 (73%) 38 (76%) 1 (2%) 1		1 (2%)	4 (8%)	(10)	1 (2%)	
Epithelium, Hyperplasia Tongue  (1) (0) (1) (0) (1) (0)  CARDIOVASCULAR SYSTEM  Heart (50) (50) (50) (49) (50) 30 (61%) 34 (68%) Fibrosis 1 (2%) Atrium, Thrombosis Myocardium, Inflammation, Chronic 1 (2%) Valve, Inflammation, Chronic 1 (2%)  NDOCRINE SYSTEM  Adrenal Cortex Hyperplasia 10 (20%) 10 (20%) 10 (20%) 11 (2		38 (76%)		36 (73%)		
Tongue (1) (0) (1) (0) (1) (0)  CARDIOVASCULAR SYSTEM  Heart (50) (50) (49) (50) Cardiomyopathy 43 (86%) 31 (62%) 30 (61%) 34 (68%) Fibrosis 1 (2%) Atrium, Thrombosis 1 (2%) Myocardium, Inflammation, Chronic 1 (2%) Valve, Inflammation, Chronic 1 (2%)  NDOCRINE SYSTEM  Adrenal Cortex (50) (50) (50) (50) (50) Hyperplasia 10 (20%) 10 (20%) 12 (24%) 8 (16%) Necrosis 1 (2%) Vacuolization Cytoplasmic 17 (34%) 14 (28%) 14 (28%) 16 (32%) Adrenal Medulla (50) (50) (50) (50) (50) Hyperplasia 3 (6%) 1 (2%) 4 (8%) 1 (2%) Hyperplasia 3 (6%) 1 (2%) 4 (8%) 1 (2%) Hyperplasia (50) (50) (49) (50) Hyperplasia (50) (50) (49) (50) Hyperplasia (47) (48) (47) (48) Parathyroid Gland (47) (48) (47) (45) Cyst		(,-)	(,-)	(,-,		
Heart (50) (50) (49) (50) Cardiomyopathy 43 (86%) 31 (62%) 30 (61%) 34 (68%) Fibrosis 1 (2%) Myocardium, Inflammation, Chronic 1 (2%) Valve, Inflammation, Chronic 1 (2%)  NDOCRINE SYSTEM  Adrenal Cortex (50) (50) (50) (50) Hyperplasia 10 (20%) 10 (20%) 12 (24%) 8 (16%) Necrosis 1 (2%) Vacuolization Cytoplasmic 17 (34%) 14 (28%) 16 (32%) Adrenal Medulla (50) (50) (50) (50) (50) Hyperplasia 3 (6%) 1 (2%) 14 (28%) 1 (2%) Alesta, Pancreatic (50) (50) (50) (50) Hyperplasia (50) (50) (50) (50) Hyperplasia (50) (50) (49) (50) Hyperplasia (47) (48) (47) (45) Parathyroid Gland (47) (48) (47) (45) Cyst		(1)	(0)	(1)	(0)	
Adrenal Cortex (50) (50) (50) (50) (50) (50) (50) Hyperplasia 10 (20%) 10 (20%) 12 (24%) 8 (16%) 12 (24%) 8 (16%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 12 (24%) 14 (28%) 14 (28%) 14 (28%) 16 (32	Cardiomyopathy Fibrosis Atrium, Thrombosis Myocardium, Inflammation, Chronic		31 (62%) 1 (2%) 1 (2%)	30 (61%)	(50) 34 (68%)	
Hyperplasia     10 (20%)     10 (20%)     12 (24%)     8 (16%)       Necrosis     1 (2%)       Vacuolization Cytoplasmic     17 (34%)     14 (28%)     14 (28%)     16 (32%)       Adrenal Medulla     (50)     (50)     (50)     (50)     (50)       Hyperplasia     3 (6%)     1 (2%)     4 (8%)     1 (2%)       Islets, Pancreatic     (50)     (50)     (49)     (50)       Hyperplasia     2 (4%)     4 (8%)       Parathyroid Gland     (47)     (48)     (47)     (45)       Cyst     1 (2%)	OCRINE SYSTEM					
Hyperplasia     10 (20%)     10 (20%)     12 (24%)     8 (16%)       Necrosis     1 (2%)       Vacuolization Cytoplasmic     17 (34%)     14 (28%)     14 (28%)     16 (32%)       Adrenal Medulla     (50)     (50)     (50)     (50)     (50)       Hyperplasia     3 (6%)     1 (2%)     4 (8%)     1 (2%)       Islets, Pancreatic     (50)     (50)     (49)     (50)       Hyperplasia     2 (4%)     4 (8%)       Parathyroid Gland     (47)     (48)     (47)     (45)       Cyst     1 (2%)	drenal Cortex	(50)	(50)	(50)	(50)	
Necrosis       1 (2%)         Vacuolization Cytoplasmic       17 (34%)       14 (28%)       14 (28%)       16 (32%)         Adrenal Medulla       (50)       (50)       (50)       (50)       (50)         Hyperplasia       3 (6%)       1 (2%)       4 (8%)       1 (2%)         Islets, Pancreatic       (50)       (50)       (49)       (50)         Hyperplasia       2 (4%)       4 (8%)         Parathyroid Gland       (47)       (48)       (47)       (45)         Cyst       1 (2%)	Hyperplasia		10 (2Ó%)	12 (24%)		
Vacuolization Cytoplasmic       17 (34%)       14 (28%)       14 (28%)       16 (32%)         Adrenal Medulla       (50)       (50)       (50)       (50)         Hyperplasia       3 (6%)       1 (2%)       4 (8%)       1 (2%)         Islets, Pancreatic       (50)       (50)       (49)       (50)         Hyperplasia       2 (4%)       4 (8%)       4 (8%)         Parathyroid Gland       (47)       (48)       (47)       (45)         Cyst       1 (2%)	Necrosis			1 (2%)	, ,	
Hyperplasia       3 (6%)       1 (2%)       4 (8%)       1 (2%)         Islets, Pancreatic       (50)       (50)       (49)       (50)         Hyperplasia       2 (4%)       4 (8%)         Parathyroid Gland       (47)       (48)       (47)       (45)         Cyst       1 (2%)				14 (28%)		
Islets, Pancreatic     (50)     (50)     (49)     (50)       Hyperplasia     2 (4%)     4 (8%)       Parathyroid Gland     (47)     (48)     (47)     (45)       Cyst     1 (2%)						
Hyperplasia       2 (4%)       4 (8%)         Parathyroid Gland       (47)       (48)       (47)       (45)         Cyst       1 (2%)			1 (2%)	4 (8%)		
Parathyroid Gland (47) (48) (47) (45) Cyst (47) (2%)		(50)			(50)	
Cyst 1 (2%)		(4=)			(45)	
Cyst 1 (2%)		(47)	(48)	(47)	(45)	
Dituitory Cland (EO) (EO) (EO)	JYSI tuitant Cland	(50)	(50)	(50)	1 (2%)	
Pituitary Gland (50) (50) (50) (50) (50)  Angiectasis 17 (34%) 24 (48%) 16 (32%) 14 (28%)						

a - Number of animals examined microscopically at site and number of animals with lesion

beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Cyst	14 (28%)	22 (44%)	16 (32%)	9 (18%)	
Fibrosis Pars Distalis, Hyperplasia	1 (2%) 14 (28%)	2 (4%) 13 (26%)	15 (30%)	10 (20%)	
Pars Intermedia, Hyperplasia Thyroid Gland	1 (2%) (50)	(49)	(49)	(50)	
Öyst C-cell, Hyperplasia	19 (38%)	20 (41%)	1 (2%) 22 (45%)	17 (34%)	
Follicle, Hyperplasia	1 (2%)	1 (2%)	4 (8%)	4 (8%)	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(50)	(50)	(50)	(50)	
Cyst	3 (6%) 8 (16%)	1 (2%) 8 (16%)	1 (2%) 13 (26%)	4 (00/)	
Hyperplasia Inflammation, Chronic	22 (44%)	11 (22%)	26 (52%)	4 (8%) 14 (28%)	
Ovary	(50)	(50)	(50)	(50)	
Atrophy	(00)	1 (2%)	(55)	(55)	
Cyst	3 (6%)	7 (14%)	6 (12%)	4 (8%)	
Uterus	(50)	(50)	(50)	(50)	
Angiectasis		- 4		1 (2%)	
Cyst	0 (40/)	2 (4%)	2 (4%)	4 (20()	
Dilatation Inflammation, Suppurative	2 (4%)	1 (2%) 1 (2%)	2 (4%)	1 (2%) 1 (2%)	
Inflammation, Chronic	1 (2%)	1 (278)		1 (2%)	
Necrosis	. (=70)		1 (2%)	. (=/3)	
Endometrium, Hyperplasia, Cystic	4 (8%)	7 (14%)	7 (14%)	13 (26%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hyperplasia	3 (6%)	1 (2%)	2 (4%)	1 (2%)	
Lymph Node Deep Cervical, Hyperplasia, Lymphoid	(5)	(3)	(2)	(6)	
Deep Cervical, Hyperplasia, Lymphold Deep Cervical, Infiltration Cellular, Histiocyte	1 (20%)	1 (33%)		1 (17%)	
Deep Cervical, Infinitation Celidial, Flistiocyte  Deep Cervical, Pigmentation				1 (17%)	
Mediastinal, Ectasia		1 (33%)		. ()	
Mediastinal, Hyperplasia, Lymphoid	1 (20%)	2 (67%)		1 (17%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Infiltration Cellular, Histiocyte				1 (2%)	

TDMS No. 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

a - Number of animals examined microscopically at site and number of animals with lesion

beta-Myrcene

**CAS Number:** 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Pigmentation, Hemosiderin				1 (2%)	
Spleen	(50)	(50)	(50)	(50)	
Atrophy	6 (12%)	2 (4%)	3 (6%)	2 (4%)	
Fibrosis			1 (2%)	- 4	
Hematopoietic Cell Proliferation	7 (14%)	12 (24%)	13 (26%)	9 (18%)	
Infarct Thymus	(49)	(48)	1 (2%) (49)	(50)	
Atrophy	46 (94%)	45 (94%)	47 (96%)	44 (88%)	
Cyst	.5 (5 . 75)	10 (0 170)	1 (2%)	(5575)	
Infiltration Cellular, Lymphocyte	1 (2%)	1 (2%)	,		
Inflammation, Chronic				1 (2%)	
Epithelial Cell, Hyperplasia	1 (2%)		1 (2%)		
NTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Cyst	2 (4%)	1 (2%)	2 (4%)	2 (4%)	
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion		1 (2%)			
MUSCULOSKELETAL SYSTEM					
Skeletal Muscle	(0)	(0)	(1)	(0)	
Inflammation, Suppurative	(0)	(0)	1 (100%)	(0)	
ERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hydrocephalus	3 (6%)	4 (8%)	6 (12%)	2 (4%)	
Hypothalamus, Compression	4 (8%)	4 (8%)	8 (16%)	5 (10%)	
Meninges, Inflammation, Chronic	(4)	(0)	1 (2%)	2 (4%)	
Spinal Cord	(1)	(0)	(0)	(0)	
ESPIRATORY SYSTEM					
Lung	(50)	(50)	(49)	(50)	
Congestion	1 (2%)	4 (00()			
Edema Inflammation	34 (68%)	1 (2%) 43 (86%)	40 (82%)	32 (64%)	
Metaplasia, Osseous	1 (2%)	43 (00%)	40 (02%)	2 (4%)	
Alveolar Epithelium, Hyperplasia	6 (12%)	3 (6%)	4 (8%)	7 (14%)	
Nose	(50)	(50)	(50)	(50)	
	` '	` '	` '	` '	

TDMS No. 99023 - 03 Test Type: CHRONIC

Species/Strain: RATS/F 344

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99023 - 03 Test Type: CHRONIC Route: GAVAGE

Species/Strain: RATS/F 344

beta-Myrcene
CAS Number: 123-35-3

Date Report Requested: 08/15/2008 Time Report Requested: 14:01:25 First Dose M/F: 03/25/02 / 03/26/02

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	
Erosion	1 (2%)				
Inflammation, Chronic Active	16 (32%)	10 (20%)	13 (26%)	10 (20%)	
Olfactory Epithelium, Degeneration	45 (90%)	44 (88%)	45 (90%)	48 (96%)	
PECIAL SENSES SYSTEM					
Ear	(0)	(3)	(0)	(0)	
Hyperplasia		1 (33%)			
Eye	(50)	(50)	(49)	(50)	
Cataract	1 (2%)		1 (2%)	1 (2%)	
Degeneration	4 (20/)			1 (2%)	
Optic Nerve, Atrophy Retina, Atrophy	1 (2%)			1 (2%) 1 (2%)	
Sclera, Metaplasia, Osseous	1 (2%)			1 (2%)	
Harderian Gland	(50)	(50)	(49)	(50)	
Atrophy	1 (2%)	1 (2%)	2 (4%)	(55)	
Hyperplasia	1 (2%)	( /	1 (2%)	1 (2%)	
Inflammation, Chronic	7 (14%)	8 (16%)	7 (14%)	2 (4%)	
Pigmentation, Porphyrin	50 (100%)	48 (96%)	48 (98%)	45 (90%)	
Zymbal's Gland	(0)	(0)	(0)	(2)	
RINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Inflammation, Suppurative, Focal	(30)	1 (2%)	(50)	1 (2%)	
Mineralization	1 (2%)	. (= /0)		. (=/5)	
Necrosis	1 (2%)	1 (2%)	1 (2%)		
Nephropathy	26 (52%)	43 (86%)	41 (82%)	44 (88%)	
Pigmentation	1 (2%)				
Papilla, Inflammation, Suppurative	1 (2%)				
Papilla, Mineralization	5 (10%)	3 (6%)	1 (2%)		
Pelvis, Inflammation, Chronic	1 (2%)	3 (6%)	4 (00()		
Renal Tubule, Cyst	2 (4%)		1 (2%)	1 (20()	
Renal Tubule, Hyperplasia Renal Tubule, Nephrosis		2 (4%)	27 (54%)	1 (2%) 45 (90%)	
Transitional Epithelium, Hyperplasia	1 (2%)	2 (4%) 12 (24%)	27 (54%) 15 (30%)	45 (90%) 19 (38%)	
Transitional Epithelium, Tryperplasia	(2/0)	12 (27/0)	(50)	(50)	
Urinary Bladder	(50)	(50)	(50)	(50)	

<sup>\*\*\*</sup> END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion